

CLAIMS

1. An oral pharmaceutical composition comprising two or more pluralities of particles, said particles comprising
5 prednisolone metasulphobenzoate, wherein the particles of each said plurality are coated with a different thickness of a pH dissolution dependent polymethacrylate material to those of the or each other plurality, whereby prednisolone metasulphobenzoate is released at different
10 locations in the intestinal tract.
2. A composition as claimed in Claim 1, wherein each of said pluralities of particles is coated with a different thickness of the polymethacrylate material, whereby
15 prednisolone metasulphobenzoate is released at locations before and after the ileo-caecal valve.
3. A composition as claimed in Claim 1 or Claim 2, wherein the thickness of polymethacrylate material
20 coating particles of each plurality of particles is of increments chosen to provide a homogeneous release profile of prednisolone metasulphobenzoate along at least one selected portion of the intestinal tract.
- 25 4. An oral pharmaceutical composition comprising two or more pluralities of particles, said particles comprising an active compound, wherein the particles of each said plurality are coated with a different thickness of a pH dissolution dependent polymethacrylate material to those
30 of the or each other plurality, whereby the active compound is released at different locations in the intestinal tract.

5. A composition as claimed in Claim 4, wherein the active compound is selected from the group consisting of prednisolone metasulphobenzoate, metronidazole and alpha-amylase.

5

6. A composition as claimed in any of the preceding claims, wherein the particles of each plurality are coated with the same coating material as those of the or each other plurality.

10

7. A composition as claimed in any of the preceding claims, wherein the polymethacrylate material comprises a methacrylic acid copolymer.

15 8. A composition as claimed in any of the preceding claims, wherein the polymethacrylate material comprises a copolymer of methacrylic acid and methyl methacrylate.

9. A composition as claimed in any of the preceding
20 claims, wherein the polymethacrylate material is selected from a copolymer of methacrylic acid and methyl methacrylate having a ratio of free carboxyl groups to ester groups of about 1:2, a copolymer of methacrylic acid and methyl methacrylate having a ratio of free
25 carboxyl groups to ester groups of about 1:1 or a mixture thereof.

10. A composition as claimed in any of the preceding claims, wherein the particles are coated with a
30 methacrylic acid copolymer of methacrylic acid and methyl methacrylate having a ratio of free carboxyl groups to ester groups of about 1:2.

11. A composition as claimed in any of the preceding claims, wherein the particle has a diameter in the range 800 to 1500 μ m.

5 12. A composition as claimed in any of the preceding claims, wherein the particles are coated with the polymethacrylate material to a theoretical weight gain on coating in the range 5% to 30%.

10 13. A composition as claimed in any of the preceding claims, wherein the particles are coated with the polymethacrylate material to a theoretical weight gain on coating in the range 10% to 25%.

15 14. A composition as claimed in any of the preceding claims, wherein the thickness of polymethacrylate material coating particles of each plurality of particles is of increments chosen to provide a homogeneous release profile of the active compound along at least one
20 selected portion of the intestinal tract.

15. A composition as claimed in any of the preceding claims, further comprising an enterically coated capsule within which the pluralities of particles are contained.

25

16. A composition as claimed in any of the preceding claims, wherein there are two pluralities of particles.

17. A composition as claimed in any of the preceding
30 claims, wherein a first plurality of particles is coated to provide a theoretical weight gain of 15% and a second plurality of particles is coated to provide a theoretical weight gain of 20%.

18. A composition as claimed in Claim 16 and Claim 17, wherein the first and second pluralities of particles are present in a ratio of about 1:3.

5 19. Use of the coating thickness of a pH dissolution dependent coating material on particles comprising an active compound to control the release profile of the active compound in the intestinal tract.

10 20. A use as claimed in Claim 19, wherein the coating material is a polymethacrylate material.

21. A use as claimed in Claim 20, wherein the polymethacrylate material comprises a methacrylic acid
15 copolymer.

22. A use as claimed in Claim 20 or Claim 21, wherein the polymethacrylate material comprises a copolymer of methacrylic acid and methyl methacrylate.

20 23. A use as claimed in any of Claims 19 to 22, wherein the polymethacrylate material is selected from a copolymer of methacrylic acid and methyl methacrylate having a ratio of free carboxyl groups to ester groups of
25 about 1:2, a copolymer of methacrylic acid and methyl methacrylate having a ratio of free carboxyl groups to ester groups of about 1:1 or a mixture thereof.

24. The use as claimed in any of Claims 19 to 23 wherein
30 the active compound is selected from the group consisting of prednisolone metasulphobenzoate, metronidazole and alpha-amylase.

25. An oral composition as defined in any of Claims 1 to 18 for use in therapy or diagnosis practised on the human or animal body.

5 26. Use of a coating material selected from:

A. a polymethacrylate material; and

B. a pH dissolution dependent coating material

10

in the preparation of a medicament as defined in any of Claims 1 to 18 for the treatment of disorders of the intestinal tract.

15 27. A use as claimed in Claim 26, wherein the coating material is a polymethacrylate material.

28. A use as claimed in Claim 26 or Claim 27, wherein the coating material is a pH dissolution dependent
20 polymethacrylate material.

29. Use of a polymethacrylate material in the preparation of a medicament as defined in any of Claims 1 to 18 for the treatment of Crohn's disease.

25

30. A method of treating a disorder of the intestinal tract of a patient, said method comprising administering to a patient an effective amount of an active compound for treating that disorder in at least two pluralities of
30 particles each coated with a different thickness of a coating material selected from

A. polymethacrylate material; and

B. a pH dissolution dependent coating material

to release the active compound at locations in the
intestinal tract at which symptoms of the disorder are
5 displayed.

31. A method as claimed in Claim 30 wherein the disorder
is Crohn's disease.

32. A method as claimed in Claim 30 or Claim 31 wherein
there are two pluralities of particles.

33. A method as claimed in any of Claims 30 to 32
wherein the active compound is prednisolone
15 metasulphobenzoate.

34. A method as claimed in any of Claims 30 to 33
wherein the coating material is polymethacrylate
material.

35. A method as claimed in any of Claims 30 to 34
wherein the active compound is released at locations
before and after the ileo-caecal valve.

36. A composition substantially as hereinbefore
described with reference to the accompanying Examples.

37. A use of the coating thickness of a pH dissolution
dependent coating material substantially as hereinbefore
30 described with reference to the accompanying Examples.

38. A use of a coating material substantially as
hereinbefore described with reference to the Examples.